EXHIBIT D

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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF CALIFORNIA

IN RE INCRETIN-BASED THERAPIES PRODUCTS LIABILITY LITIGATION

As to All Related and Member Cases

Case No. 13-md-2452-AJB-MDD

DEFENDANT MERCK SHARP & DOHME CORP.'S AMENDED RESPONSES AND OBJECTIONS TO PLAINTIFFS' GENERAL CAUSATION REQUESTS TO PRODUCE

Judge: Hon. Anthony J. Battaglia
Magistrate: Hon. Mitchell D. Dembin

Defendant Merck Sharp & Dohme Corp. ("Merck"), pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure, sets forth below its Responses and

Objections to Plaintiffs' General Causation Requests to Produce.

PRELIMINARY STATEMENT

In accordance with Federal Rule of Civil Procedure 26 and the Orders of this Court, Merck has undertaken a reasonable inquiry to identify non-privileged documents responsive to Plaintiffs' document requests, including, *inter alia*, the following actions:

- Pursuant to the agreed-upon ESI protocol, Merck has identified custodial files of employees from various departments most likely to contain information relevant for general causation purposes, and, in the case of Jose Vega, M.D., because requested by Plaintiffs' counsel. These custodians are as follows:
    (1) Richard Clay, M.D., Director, head of safety/toxicology in the Discovery & Preclinical Sciences Division.
    (2) Lou Ann Eader, Ph.D., Senior Principal Scientist, Regulatory Liaison, Current Regulatory Liaison for JANUVIA® and JANUMET® in the United States.
    (3) Samuel Engel, M.D., Executive Director, Clinical Research with a focus on sitagliptin.
    (4) Georgianna Harris, Ph.D., former Executive Director, then Distinguished Scientist in Regulatory Affairs, managed the Regulatory Liaison for sitagliptin.
    (5) Barry Goldstein, M.D., Ph.D., former Therapeutic Area Head for Diabetes at Merck.
    (6) Keith Kaufman, M.D., Project Leader for JANUVIA® and JANUMET®.
    (7) Robert Silverman, M.D., Ph.D., former Distinguished Scientist and manager in Regulatory Affairs, managed the Regulatory

Liaison for sitagliptin at an earlier point.

(8) Peter Stein, M.D., Vice President, Clinical Research, Diabetes and Endocrinology.

(9) Jenny Yu, M.D., Distinguished Scientist, Drug Safety/Pharmacovigilance individual assigned to sitagliptin.

(10) Jose Vega, M.D., Vice President, Chief Safety Office & Clinical Risk Management.

In accordance with the ESI Protocol agreed to by the parties and entered by the Court, Merck has used the agreed-upon ESI search terms to cull electronically collected data from these custodians, and has produced relevant, non-privileged documents identified through that process.

- Merck has queried its eDossier database to collect and produce its IND and NDA files for JANUVIA® and JANUMET® through February 28, 2014. Merck has likewise queried its eDossier database to collect its EMA regulatory files for JANUVIA® and JANUMET® through February 28, 2014, and has produced the same.
- Merck has identified and produced its FDA-approved U.S. product labels and medication guides for JANUVIA® and JANUMET® through February 28, 2014.
- Merck has queried its Argus database for global adverse event reports (MARRS) to collect, and has produced, MedWatch forms for spontaneous, postmarketing global adverse event reports of pancreatitis and pancreatic cancer for sitagliptin through February 28, 2014. Merck has also produced so-called "native" or "quasi-native" data files extracted from its database for global adverse event reports of pancreatitis and pancreatic cancer for sitagliptin received through February 28, 2014. This data includes fields used by Merck

in the ordinary course of business, but does not include fields containing personal identifying information. Merck has produced the "quasi-native" data extraction in Access Database format.

- Merck will also query MARRS to collect MedWatch forms for global clinical study adverse event reports of pancreatitis and pancreatic cancer for sitagliptin through February 28, 2014, and has produced the same.
- Merck produced Standard Operating Procedures ("SOPs") relating to adverse event reporting requested by Plaintiffs in connection with the 30(b)(6) deposition of Linda Hostelley. Merck has undertaken a reasonable investigation to identify, and has produced, additional SOPs relating to the conduct and evaluation of clinical and preclinical data and observational studies.
- Through reasonable investigation Merck has identified, and has produced, organizational charts for the clinical, preclinical, and drug safety areas that cover JANUVIA® and JANUMET®.
- Through reasonable investigation with appropriate Merck employees with knowledge of the materials relating to Merck's preclinical, clinical and observational studies for JANUVIA® and JANUMET®, Merck has identified and has produced Merck final study reports and trial protocols for its clinical, preclinical, animal and observational studies from the sitagliptin development program, to the extent not already produced in connection with the IND and NDA files for JANUVIA® and JANUMET®. To the extent not already produced, Merck has produced or made available for inspection data sets, raw data, and/or other underlying data, specimens, slides, or documentation for particular studies as may be reasonably requested by Plaintiffs subject to additional meet-and-confer among the parties. A list has been created of

Merck's preclinical, clinical, and observational studies for JANUVIA® and JANUMET®. The list includes study numbers and titles. Merck has also supplemented the list to include a Bates range for the documents that correspond to each study.

- Through reasonable investigation Merck has identified internal SharePoint sites that are likely to contain responsive documents related to general causation and has produced relevant, non-privileged documents from these sources. These include documents relating to JANUVIA® and JANUMET® stored on the SharePoint sites for the JANUVIA® Product Development Team ("PDT") (which also includes documents from the Risk Management Safety Team ("RMST")) and the Safety Review Committee ("SRC"). The JANUVIA® PDT is a cross-functional team responsible for coordinating and executing the development process for sitagliptin, including issues related to safety, efficacy, and labeling. The RMST is a subteam of the PDT, and is responsible for overall risk management and safety signal evaluation for JANUVIA® and JANUMET®, including pancreatic safety issues. The SRC is responsible for reviewing preclinical and clinical safety-related findings impacting both developmental and marketed products, as well as for reviewing emerging signals and findings from post-marketing safety assessments.
- Through reasonable investigation Merck has identified, and has produced, Adverse Experience Review Process Memos for sitagliptin.
- Based on information and belief, Merck did not distribute any Dear Healthcare Professional Letters (as set forth in 21 CFR 200.5 and related FDA guidances) relating to JANUVIA® or JANUMET® and pancreatic safety issues. However, through reasonable investigation, Merck has identified, and has produced certain communications sent to scientists and healthcare

professionals about labeling and safety issues relating to JANUVIA® and JANUMET®, exclusive of marketing materials.

- Merck has undertaken a reasonable investigation to identify, and has produced, document retention policies that apply to documents relating to the clinical and preclinical development and safety of JANUVIA® and JANUMET®.
- Merck has queried its internal tracking databases for information relating to compensation paid by Merck to the individuals identified by Plaintiffs in Request No. 65 and has produced relevant, non-privileged information, if any, as identified by those searches.

GENERAL OBJECTIONS

The following General Objections are incorporated into each of the specific objections and responses that follow. Stating a specific objection or response shall not be construed as a waiver of any of Merck's other objections.

a. Merck objects to all definitions, instructions, and requests insofar as they seek production or disclosure of documents or information subject to the attorney-client privilege, work product doctrine, or any other applicable privilege, rule, doctrine or immunity, whether created by statute or common law. All requests have been read to exclude discovery of such privileged information. Inadvertent production of any such information shall not constitute a waiver of any privilege or any other ground for objecting to discovery with respect to such information, nor shall inadvertent production waive the right of Merck to object to the use of any such information in any proceeding.

b. Merck's objections and responses to the requests herein that use the terms "You," "Your," or "Defendant" construe those terms as referring to Merck Sharp & Dohme Corp.